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SENATE

REPORT
101-242

FDA REVITALIZATION ACT

FEBRUARY 1 (legislative day, JANUARY 23), 1990.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 845]

The Committee on Labor and Human Resources, to which was referred the bill (S. 845) to amend the Federal Food, Drug and Cosmetic Act to revitalize the Food and Drug Administration, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

CONTENTS

		Page
I.	Summary of the bill	7
II.	Background and need for legislation	8
III.	Committee views	10
IV.	Committee action	17
V.	Cost estimate	17
VI.	Regulatory impact statement	20
VII.	Section-by-section analysis	20
VIII.	Changes in existing law	25

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS

(a) SHORT TITLE.—This Act may be cited as the "FDA Revitalization Act".

(b) TABLE OF CONTENTS.—The table of contents is as follows:

Sec. 1. Short title, table of contents.
Sec. 2. References to the Federal Food, Drug, and Cosmetic Act.

TITLE I—CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY

Sec. 101. Consolidated administrative and laboratory facility.

TITLE II—SENIOR SCIENTIFIC SERVICE

Sec. 201. Senior Scientific Service.

39-010

S543-1

TITLE III—RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS

Sec. 301. Recovery and retention of fees for FOIA requests.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

Sec. 401. Small business training and technical assistance.

TITLE V—BIOTECHNOLOGY DEMONSTRATION PROJECT

Sec. 501. Biotechnology demonstration project.

TITLE VI—TRAINING AND LOAN REPAYMENT PROGRAMS

Sec. 601. Training and loan repayment programs.

TITLE VII—SCIENTIFIC REVIEW GROUPS

Sec. 701. Scientific review groups.

TITLE VIII—HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE

Sec. 801. Human Food Safety, Technology, and Nutrition Advisory Committee.

TITLE IX—AUTOMATION OF FDA

Sec. 901. Automation of FDA.

TITLE X—COMPENSATION AND EMPLOYMENT REQUIREMENTS FOR FDA AND EPA SCIENTISTS

Sec. 1001. Compensation and employment requirements for FDA and EPA scientists.

TITLE XI—FUNDING FLOOR FOR FDA

Sec. 1101. Funding floor for FDA.

TITLE XII—PLAN OF MANAGEMENT INITIATIVES

Sec. 1201. Plan for management initiatives.

SEC. 2. REFERENCES TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)

TITLE I—CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY

SEC. 101. CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY.

Chapter VIII (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 710. CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY.

"(a) AUTHORITY.—The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

"(b) AWARDING OF CONTRACT.—The Secretary shall solicit contract proposals under subsection (a) from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal government and that allow for the use of donated land, Federally owned property, or lease-purchase agreement. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal government over the duration of the contract as compared to the government purchase price including borrowing by the Secretary of Treasury.".

TITLE II—SENIOR SCIENTIFIC HEALTH SERVICE

SEC. 201. SENIOR SCIENTIFIC HEALTH SERVICE.

Part A of title III of the Public Health Service Act is amended by inserting after section 301 (42 U.S.C. 241) the following new section:

"SEC. 301A. SENIOR SCIENTIFIC HEALTH SERVICE.

"(a) ESTABLISHMENT.—The Secretary may establish a Senior Scientific Health Service (hereinafter in this section referred to as the 'Service').

"(b) MEMBERSHIP.—

"(1) CIVIL SERVICE.—An individual chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

"(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on distinction and achievement of the person in the field of biomedical research or clinical research evaluation.

"(c) DUTIES.—A member of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

"(d) COMPENSATION.—An individual selected to serve on the Service by the Secretary under subsection (b) shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

"(e) RETIREMENT.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health Service Corps may be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal Government.".

(c) Section 5948(g)(1) of title 5, United States Code, is amended—

(1) by striking out "or" at the end of subparagraph (H);

(2) by striking out "and" at the end of subparagraph (I), and inserting in lieu thereof "or"; and

(3) by adding at the end thereof a new subparagraph as follows:

"(J) section 301A of the Public Health Service Act, relating to the Senior Scientific Health Service; and".

TITLE III—RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS

SEC. 301. RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS.

Chapter VII (21 U.S.C. 371 et. seq.) (as amended by section 101) is further amended by adding at the end thereof the following new section:

"SEC. 711. RECOVERY AND RETENTION OF FEES FOR FREEDOM OF INFORMATION REQUESTS.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may—

"(1) set and charge fees to recover all reasonable costs incurred in processing requests made under section 552 of title 5, United States Code, for records obtained or created under this Act or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

"(2) retain all fees charged for such requests; and

"(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

"(b) USE OF FEES.—The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1). Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this Act.

"(c) WAIVER OF FEES.—Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5, United States Code.".

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

SEC. 401. SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE.

Chapter VII (21 U.S.C. 371 et seq.) (as amended by sections 101 and 301) is further amended by adding at the end thereof the following new section:

"SEC. 712. SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices, drugs, cosmetics, and foods to assist the manufacturers in complying with this Act.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $18,000,000 for each of the fiscal years 1990 through 1992.".

TITLE V—BIOTECHNOLOGY DEMONSTRATION PROJECT

SEC. 501. BIOTECHNOLOGY DEMONSTRATION PROJECT.

Chapter VII (21 U.S.C. 371 et seq.) (as amended by sections 101, 301, and 401) is further amended by adding at the end thereof the following new section:

"SEC. 713. BIOTECHNOLOGY DEMONSTRATION PROJECT.

"(a) IN GENERAL.—The Secretary shall establish and carry out a demonstration project under which the Secretary shall use the facilities of a public or private cooperative, with the permission of any such cooperative and in conjunction with such cooperative, to promote the development of biotechnology.

"(b) REGULATIONS.—The Secretary shall issue such regulations as are necessary to carry out this section.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 1990 and such sums as are necessary for each of the fiscal years 1991 and 1992.".

TITLE VI—TRAINING AND LOAN REPAYMENT PROGRAMS

SEC. 601. TRAINING AND LOAN REPAYMENT PROGRAMS.

The Act (21 U.S.C. 301 et seq.) is amended by adding at the end thereof the following new chapter:

"CHAPTER X—TRAINING AND LOAN REPAYMENT PROGRAMS

"Subchapter A—Training Program

"SEC. 1001. AUTHORITY.

"The Secretary may make grants to, or enter into contracts with, public or nonprofit academic institutions (including schools of medicine, dentistry, pharmacy, public health, and food science) to enable such institutions to design and develop core curriculum programs that will be used to train individuals in the field of regulatory review.

"SEC. 1002. REQUIREMENTS.

"(a) IN GENERAL.—No grant shall be awarded under this subchapter unless—

"(1) the institution has submitted to the Secretary an application for a grant and the Secretary has approved the application; and

"(2) the institution provides, in such form and manner as the Secretary shall be regulation prescribe, assurances satisfactory to the Secretary that individuals receiving funds through the institution under such grants will meet the service requirement of section 1004.

"(b) APPLICATION.—An application for a grant submitted under subsection (a) shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

"SEC. 1003. USE OF GRANTS.

"An institution that receives a grant under this subchapter—

"(1) shall use such grant to—

"(A) design and develop a core curriculum program that has as its primary emphasis regulatory review; and

"(B) train health professionals and scientists in regulatory review; and

"(2) may use such grant to provide stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), to individuals who participate in the regulatory review program developed with funds provided under this subchapter.

"SEC. 1004. REQUIREMENT OF SERVICE.

"(a) IN GENERAL.—Each individual who receives funds from an institution through a grant provided under this subchapter shall, in accordance with subsection (c), serve an obligated period of time as an employee of the Food and Drug Administration.

"(b) PERIOD OF REQUIRED SERVICE.—For each month for which an individual receives funds in accordance with subsection (a), such individual shall remain employed for 2 months with the Food and Drug Administration.

"(c) COMPLIANCE.—The requirements of this section shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of the training of such individual under the grant received under this subchapter, as the Secretary shall by regulation prescribe.

"(d) FAILURE TO COMPLY.—If any individual to whom this section applies fails, within the period prescribed under subsection (c), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with a formula prescribed through regulations issued by the Secretary.

"SEC. 1005. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to carry out this subchapter $4,000,000 for fiscal year 1990 and such sums as may be necessary for each of the fiscal years 1991 through 1992.

"Subchapter B—Loan Repayment Program

"SEC. 1011. LOAN REPAYMENT PROGRAM.

"The Secretary shall establish a loan repayment program under which the Secretary shall repay loans incurred by individuals to obtain training in regulatory review in exchange for the individuals serving a period of time as employees of the Food and Drug Administration.

"SEC. 1012. ADMINISTRATION.

"(a) REGULATIONS.—Not later than 1 year after funds are first made available to carry out this subchapter under section 1013, the Secretary shall issue such regulations that are necessary to carry out this subchapter, including regulations prescribing eligibility for the loan repayment program, the method of disseminating applicants to participate in the program, the content of a contract entered into to participate in the program, costs that are eligible for payment through the contract, and such other information as is necessary to carry out the program.

"(b) RELATIONSHIP TO NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.—The Secretary shall carry out the loan repayment program established under this subchapter, to the extent practicable, in a manner that is consistent with the National Health Service Corps Loan Repayment Program established under section 338B of the Public Health Service Act (42 U.S.C. 2541-1).

"(c) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, an individual who has entered into a written contract with the Secretary under this subchapter, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

"SEC. 1013. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to carry out this subchapter $2,000,000 for each of the fiscal years 1990 through 1992.".

TITLE VII—SCIENTIFIC REVIEW GROUPS

SEC. 701. SCIENTIFIC REVIEW GROUPS.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 903. SCIENTIFIC REVIEW GROUPS.

Without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

"(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this Act); and

"(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.".

TITLE VIII—HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE

SEC. 801. HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE.

Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 413. HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee which shall be known as the 'Human Food Safety, Technology, and Nutrition Advisory Committee' (hereinafter in this section referred to as the 'Advisory Committee').

"(b) COMPOSITION.—

"(1) IN GENERAL.—The Advisory Committee shall consist of 15 members appointed by the Secretary.

"(2) MEMBERSHIP.—In making appointments under paragraph (1), the Secretary shall—

"(A) consult with the Secretary of Agriculture; and

"(B) ensure that the membership of the Advisory Committee includes—

"(i) consumers who are not otherwise represented under this subparagraph;

"(ii) representatives of the food industry;

"(iii) experts in the field of food technology and food production;

"(iv) experts in the application of biotechnology to food products;

"(v) experts in the field of nutrition; and

"(vi) experts in the field of food safety.

"(c) DUTIES.—The Advisory Committee shall advise the Secretary and the Commissioner of Food and Drugs on issues involving food for human consumption, including issues relating to—

"(1) food technology and production;

"(2) food research and development;

"(3) biotechnology and food products;

"(4) food safety;

"(5) the relationship between diet, nutrition, and health; and

"(6) health-related claims for food for human consumption.

"(d) TERMS.—A member of the Advisory Committee shall be appointed for a term of 3 years, except that of the members first appointed, 5 members shall be appointed for a term of 1 year, 5 members shall be appointed for a term of 2 years, and 5 members shall be appointed for a term of 3 years, as determined by the Secretary.

"(e) SUPPORT.—The Commissioner of Food and Drugs shall provide the Advisory Committee with such professional and clerical staff and information as may be necessary for the Advisory Committee to carry out this section.

"(f) TRAVEL EXPENSES.—A member of the Advisory Committee, while so serving away from the home or regular place of business of the member, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized under section 5703 of title 5, United States Code, for employees serving intermittingly."

TITLE IX—AUTOMATION OF FDA

SEC. 901. AUTOMATION OF FDA.

Chapter VII (21 U.S.C. 371 et seq.) (as amended by sections 101, 301, 401, and 501 of this Act) is further amended by adding at the end thereof the following new section:

"SEC. 714. AUTOMATION OF FOOD AND DRUG ADMINISTRATION.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this Act.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated each fiscal year such sums are necessary to carry out this section.".

TITLE X—COMPENSATION AND EMPLOYMENT REQUIREMENTS FOR FDA AND EPA SCIENTISTS

SEC. 1001. COMPENSATION AND EMPLOYMENT REQUIREMENTS FOR FDA AND EPA SCIENTISTS.

The Director of the Office of Personnel Management shall take such action as is necessary to ensure, to the extent practicable, that the level of compensation and employment requirements are comparable for scientists employed by the Food and Drug Administration and scientists employed by the Environmental Protection Agency.

TITLE XI—FUNDING FLOOR FOR FDA

SEC. 1101. FUNDING FLOOR FOR FDA.

Notwithstanding any other provisions of law, there shall be appropriated no less than $500,000,000 each fiscal year to carry out the activities of the Food and Drug Administration.

TITLE XII—PLAN OF MANAGEMENT INITIATIVES

SEC. 1201. PLAN OF MANAGEMENT INITIATIVES.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall contract for a study of the management initiatives undertaken to assess, prioritize, and improve the efficiency and productivity of the activities of the Food and Drug Administration. Such plan shall provide for identifiable and measurable goals and objectives.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary in each of the fiscal years 1990 and 1991.

I. SUMMARY OF THE BILL

The FDA Revitalization Act of 1989 amends the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and makes additional provisions as follows:

A consolidated FDA administrative and laboratory facility.—The Secretary of Health and Human Services is given authority, in consultation with the General Services Administration, to enter into contracts for the design, construction, and operation of a consolidated facility for the Food and Drug Administration (FDA).

Senior scientific health service.—The Secretary may establish a senior scientific health service with salaries at up to 110 percent of present levels.

Recovery and retention of fees for freedom of information activities.—FDA is authorized to fund its activities required by the Freedom of Information Act by charging and retaining fees for FOIA requests.

Small business training and technical assistance.—FDA is directed to establish an office to provide technical and other nonfinancial assistance to small manufacturers of FDA-regulated products. Eighteen million dollars is authorized for each fiscal year from 1990 through 1992.

Biotechnology demonstration project.—The Secretary shall establish and conduct a demonstration project, using the facilities of a public or private cooperative, to promote the development of biotechnology. Ten million dollars is authorized for this purpose in FY90 and sums as necessary in FY91 and 92.

Training in regulatory review and loan repayment programs.—A. The Secretary may make grants or contracts with academic institutions to design and develop curricula in the field of regulatory review. Grants may be used both for curriculum design and training; individuals receiving training grants under this section are obligated to serve as FDA employees for a period equal to two months for each month funds are received. Four million dollars is authorized for this purpose in FY90 and sums as necessary in FY91 and 92.

B. The Secretary shall establish a loan repayment program under which the Secretary shall repay loans incurred by individ-

uals to obtain training in regulatory review in exchange for the individuals' serving a period of time as FDA employees. The program will be carried out in a manner consistent with the National Health Services Corps loan repayment program, and regulations implementing the program will be issued within one year. Two million dollars is authorized for each fiscal year from 1990 through 1992.

Scientific review groups.—The Commissioner of Food and Drugs may establish technical and scientific review groups as needed to carry out the work of FDA and may appoint and pay the members of these groups.

Human Food Safety, Technology, and Nutrition Advisory Committee.—The Secretary shall establish a committee composed of 15 members, including food experts and consumer representatives, to advise the Commissioner and Secretary on matters relating to food technology, production, research and development, biotechnology, food safety, nutrition, and health-related claims.

Automation of FDA.—The Secretary shall automate appropriate FDA activities to ensure timely review. Sums for this purpose as necessary are authorized for each fiscal year.

Compensation and employment requirements for FDA and EPA scientists.—The Director of the Office of Personnel Management shall ensure that FDA and the Environmental Protection Agency (EPA) have comparable pay and employment requirements for scientists.

Funding floor for FDA activities.—Other laws notwithstanding, no less than $500 million shall be appropriated in each fiscal year for FDA.

Plan of management initiatives.—The Secretary, acting through the FDA Commissioner, is required to enter into a contract within one year to study the management of FDA to improve efficiency and productivity. Funds as necessary for this purpose are authorized for fiscal years 1990 and 1991.

II. Background and Need for Legislation

FDA's mission is to ensure that food is safe, pure, and wholesome; that human and animal drugs, biological products, and medical devices are safe and effective; that cosmetics are safe; and that radiological products and procedures for their use do not result in unnecessary exposure.

Clearly, FDA's mission and the activities the agency undertakes to achieve that mission are vitally important to the public health, to technological development, and, ultimately, to the economy. The products under FDA's jurisdiction account for hundreds of billions of dolars spent annually by consumers. These products are diverse, and the activities undertaken by FDA to protect the consumers who use them embrace a wide range of scientific, educational, and regulatory effots. In carrying out these activities, FDA makes important contributions to the technological development of new products through research, standard setting and guidance. Moreover, FDA review and postmarketing surveillance strongly affect consumer confidence in these products and willingness to use them.

In recent years, FDA has been faced with the regulation of products derived through increasingly complex technologies, and, at the same time, with budgetary constraints. Unanticipated crises such as tampering incidents and outbreaks of foodborne illness have added to these pressures. Today, FDA needs additional resources on an immediate basis to fulfill its basic mission and to strengthen its readiness to meet the challenges that confront it.

FDA must be able to recruit and retain excellent scientists. Historically, the agency has been able to attract very fine and highly dedicated personnel. However, it is unrealistic to expect that FDA and other government agencies that require a skilled scientific component can continue to attract these individuals without vigorous efforts to offer them salaries that are comparable to salaries offered by universities and private industry and to improve their status. An important feature of this bill is that is makes possible a prestigious Senior Scientific Health Service with the ability to pay salaries up to 110 percent of present salaries.

This bill would also make possible a greatly improved working environment for FDA headquarters personnel by authorizing the Secretary of Health and Human Services, in consultation with the General Services Administration, to take steps for the design, construction, and operation of a cost effective consolidated administrative and laboratory facility. Currently, these personnel, who comprise the nerve center of the agency's activities, are scattered among 23 buildings at seven different sites in the Washington, D.C. area. For the most part, these are old buildings, lacking adequate wiring and ventilation systems. Coordinating agency activities among personnel at these different sites is cumbersome, and transportation from one site to another for meetings and consultation is costly and time-consuming. A consolidated FDA facility would allow the agency to streamline its headquarters activities and operate with greater efficiency.

Other provisions of the bill are also intended to assure a more efficient FDA. Within a year of enactment, a management study is required to be undertaken for the purpose of assessing, giving priority to, and improving the efficiency of FDA's activities. The bill provides as well for automation of appropriate FDA activities to ensure timely review of new products. FDA has taken preliminary steps toward automating certain activities in its review of new drugs; this provision would help to complete the automation and shorten the review process.

The bill would enable FDA to complement its activities with outside expertise in two ways. (1) The FDA Commissioner is authorized to establish technical and scientific review groups as needed. The agency made use of such review groups in the first phase of its precedent-setting review of over-the-counter drugs. In the future, groups of this kind could augment the work of overburdened review staffs. (2) The Secretary is required to establish a Human Food Safety, Technology, and Nutrition Advisory Committee to advise FDA on matters relating to food technology, production, research and development, biotechnology, food safety, and food labeling claims related to health and nutrition. Members would include consumer and industry representatives as well as food experts, and the Committee would function in much the same way as FDA's

highly respected advisory ccommittees in the areas of drugs, biologics, and medical devices. The recommendations of these expert bodies are instrumental in helping to resolve complex and sensitive issues that FDA must deal with in an informed and impartial way.

Two provisions of the bill enable FDA to offer important assistance in the area of new product develpment. (1) FDA is directed to establish an office to provide technical and other nonfinancial assistance to small manufacturers of products regulated by the agency. Small businesses have been the source of some important breakthrough drugs and medical devices. Frequently, however, because of their size and financial limitations, they may lack expertise in the development of an investigational product in accordance with the FFDC Act. FDA is able to provide invaluable, time-saving guidance to such firms, and establishment of an office for this specific purpose would facilitate the process. (2) The Secretary is directed to establish and conduct a demonstration project to promote the development of biotechnology. In the second half of this century, new techniques of biotechnology have created opportunities to develop products that have never been possible before, including important therapies, vaccines, diagnostic tests and foods. The United States currently leads the world in biotechnology research, and the field holds enormous commercial promise. However, this country faces competition from nations such as Japan and European Community nations that emphasize commercialization and the results of research. It is strongly in our interest to look for opportunities such as this demonstration project to promote the development of biotechnology.

Toward assuring adequate financial resources for FDA, the FDA Revitalization Act places a $500 million floor on the agency's annual budget appropriation. It also provides financial relief in one important area by enabling the agency to charge fees to recover the full cost of responding to requests for information under the Freedom of Information Act (FOIA). The agency could retain these funds and apply them solely to its FOIA activities, making these activities virtually self-sufficient. Currently, FDA, which has one of the heaviest FOIA workloads among government agencies, charges requestors an estimated one-tenth of its actual processing costs for FOIA requests, and these funds must go into the U.S. Treasury. In 1988, for example, FDA remitted to the Treasury FOIA receipts of $451,000. However, in that year, the agency actually absorbed costs of $5.6 million for handling the 40,000 FOIA requests it received.

III. Committee Views

The Committee strongly supports efforts to enhance the Food and Drug Administration to ensure that they continue to have the resources necessary to provide consumer protection and technology development of new foods, drugs, devices, and cosmetics. While the Food, Drug, and Cosmetic Act of 1938 continues to serve as the basic law which establishes the FDA's authority and responsibilities, the role of the agency has evolved since that time.

Today, FDA has the responsibility for regulating more than $700 billion worth of goods sold annually to Americans—constituting about 25 percent of the total expenditures for personal consump-

tion in the United States each year. FDA must accomplish its vast and complex tasks with very limited resources—over 7,000 employees nationwide and an annual budget of only $587 million. For these reasons, the Committee supports S. 845 which provides additional resources, both financially and legislatively, to allow FDA to continue its efforts into the 21st century.

TITLE I—REAL PROPERTY

Section 101 of Title I amends Chapter VIII of the Federal Food, Drug and Cosmetic Act by adding authority for the Secretary, in consultation with the Administrator of the General Services Administration to enter into a contract for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility. In addition, the Section requires that the Secretary give priority to a contract for the facility that is most cost effective to the Federal government, and results in a net cost savings to the Federal government over the duration of the contract, as compared to the government purchase price including borrowing by the Secretary of the Treasury.

Currently, the FDA has staff in about 1.3 million square feet of space rented throughout the Washington metropolitan area. FDA headquarter employees are located in 23 different buildings on seven different sites in the Washington area from the District of Columbia to Silver Spring and from Beltsville to Rockville. Furthermore, some of those buildings, like the Center for Food Safety and Applied Nutrition's laboratory facilities, are inadequate and outmoded. This building, which was last remodeled over 25 years ago, has difficulty meeting the Agency's own standards for good laboratory practices.

The Chairman and Ranking member of the Committee were joined by the Chairman and Ranking member of the Subcommittee on Agriculture, Rural Development, and Related Agencies, Committee on Appropriations in a request to the GAO for an analysis of the resource needs of the FDA. That report was submitted to the Senate on September 16, 1989.

The Committee believes that this current fragmentation of FDA personnel and the continued reliance on outmoded laboratory facilities had delayed the timely and effective handling of many time sensitive and emergency matters. This current situation has contributed to increase timeframes for product review of premarket applications of drugs, biological products, food additives, and medical devices. The current widespread scattering of FDA personnel has resulted in inefficiencies beyond the control of the Agency's senior management. The physical separation of facilities has unduly increased travel time and inhibited the exchange of ideas, information, and scientific expertise among FDA scientists. This exchange of ideas is crucial if the FDA is to undertake successfully its mission to protect the public health. For example, many FDA regulatory issues, like health fraud, orphan products, involve all FDA centers rather than one or two individual program areas.

Historically the FDA has had difficulty in obtaining and maintaining adequate facilities due to lack of funding for new construction and replacement of outdated facilities. The Agency has also

been hampered by onerous bureaucratic procedures that have prevented it from directly acquiring new facilities. The Committee believes that consolidation of Agency facilities will help to establish FDA as a major research and biomedical institution. Consolidation will also result in greater productivity and will enable FDA scientific reviewers and researchers to communicate more easily with regulatory staff and administrators in order to ensure a uniform approach to problem solving.

The Committee believes that the provisions of Title I will provide the FDA with the appropriate involvement of the GSA and the ability to obtain a state of the art facility for administrative and laboratory use. Present outdated laboratory facilities have hampered the FDA's ability to respond more quickly to public health priorities such as AIDS. The Committee believes that given the importance of its mission to protect the public health, the FDA needs to be consolidated in a building that contains state of the art equipment. The Committee believes that enactment of Title I of S. 845 will enable FDA reviewers and researchers to gain greater access to modern scientific facilities and respond to rapidly advancing AIDS technology.

TITLE II—SENIOR BIOMEDICAL SCIENTIFIC SERVICE

The Committee supports the establishment of a Senior Biomedical Scientific Service outside of the competitive civil service. The members of the service would be appointed based on the distinction and achievement in biomedical research, clinical research evaluation and behavioral research. The Service would be comprise of a limited number of individuals in the Public Health Service who would be assigned to biomedical research, behavioral research, or clinical research evaluation. In addition, individuals in this Service may also be assigned to supervise other scientists involved in such research.

The members of the Service would be compensated at a rate not to exceed 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule, as described in section 5512 of title 5, USC.

The Committee's decision to support the establishment of the service is an outgrowth of concern that salary caps are causing severe problems in recruiting and retaining top scientists in the Public Health Service. The Committee feels that the service is necessary to maintain the national and international leadership in biomedical, behavioral and clinical research in the PHS. The Senior Biomedical Service would be available for senior scientists at the Alcohol, Drug Abuse, and Mental Health Administration, the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health.

TITLE III—RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS

Title III provides the authority for the FDA to set and retain fees that are charged to fulfill requests made under the Freedom of Information Act (5 U.S.C. 552). The Committee expects that any increase in current fees will not exceed the cost to provide such services nor will any future increase be greater than the increase in

overhead cost associated with providing such service. However, whenever the FDA increases fees the Commissioner shall give notice for comment in the Federal Register with an explanation of the increase and the fee structure before they become effective. The Committee expects that the retention of FOIA fees will be used to carry out and improve the provision of services to FOIA requesters. In addition, the Committee had directed that these fees not be used in carrying out any other provisions of the Food, Drug, and Cosmetic Act.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

The Committee is aware of the special contributions that small manufacturers make to produce innovative products for the nation. In the medical device industry, the Committee has been informed that over 95 percent of medical device manufacturers have less than 500 employees and about 63 percent have less than 50 employees. To support training and technical assistance to small business, the Committee supports title IV which authorizes $18,000,000 in fiscal year 1990 through fiscal year 1992 for such activities.

The Committee acknowledges that there are good activities currently administered by the Center for Devices and Radiological Health at the Food and Drug Administration, which provide several types of services to small businesses that manufacture medical devices. The workshops, educational video tapes, reference manuals and personal contact made available through telephone or correspondence in order to answer questions of manufacturers, are recognized by the Committee as critical to the continued success of innovative small businesses.

Since most small businesses do not have the resources to keep up with the extensive number of government regulations required by the agency, the Committee directs that funds under this section be used to establish similar programs in all of the centers at the FDA.

TITLE V—BIOTECHNOLOGY DEMONSTRATION PROJECTS

Chapter VIII of the Federal Food, Drug, and Cosmetic Act is further amended to provide the Secretary the authority to establish and implement a demonstration project and requires that regulations be issued describing how only public or private cooperative may use the facilities to perform the activities authorized under the Act. The Committee believes that this Nation is at the beginning of a new frontier which will shape the economic future of this country for many decades to come. This frontier is in the field of biotechnology, which holds enormous potential for the development of new products in medicine, agriculture and the environment.

The Committee recognizes the development of products in biotechnology requires the use of highly specialized facilities, some requiring impervious walls, specialized air handling systems and drainage connected to tanks that can be steam-sterilized in order to prevent accidents. The Committee further realizes that while such facilities would be exremely expensive for small research firms to construct, many firms could afford to lease space and equipment if it were made available.

Due to the enormous resources being dedicated in this field by foreign countries and the high degree of competitiveness that has emerged for the development of biotechnology products, the Committee believes that is a need for a facility to be developed in the United States where small research organizations who are unable to finance the construction of extremely expensive space required for containment of the products of biotechnology, can come together to share that space and the sophisticated scientific equipment required of this work. Through use of such a facility, the Committee believes that firms not only would have opportunities to develop new research ideas, they would be able to dramatically reduce the time from research to market, a need most commonly identified by economic analysts are being critical to the future success of the United States in this major developing industry.

The Committee has been informed that such a facility already exists. The government owns approximately 400,000 square feet of this high-level containment. The Committee understands that it is part of a very active and highly respected biological research facility in central Arkansas, the National Center for Toxicological Research, NCTR. Constructed in the early 1950's for the containment of biological weapons as part of the U.S. Army's Pine Bluff Arsenal, the Committee understands that the entire facility was demilitarized in 1970–71 and has been turned over the research on toxic compounds.

The Committee believes that a key element of this type of project is the co-location on site of representatives of the regulatory agencies responsible for approving biotechnology products, the FDA, EPA, USDA, and U.S. Patent Office. The Committee recognizes the importance of having prospective review of scientific plans to assure that the necessary types of research will be conducted with the aim of producing an approvable application in the shortest time possible. The Committee has been informed that ample space and facilities exist in that immediate area to house these additional needs at the NCTR site. The costs of renovation would eventually be recovered through the leases to industrial tenants.

TITLE VI—TRAINING AND LOAN REPAYMENT PROGRAMS

The Committee believes that in order to continue to protect the public health and maintain its leadership more trained scientists must be trained in regulatory review medicine. Therefore, S. 845 provides the Commissioner of the Food and Drug Administration the authority to make grants to public and private non-profit institutions to develop programs to train health professionals and scientists in the field of regulatory review medicine. Such programs will be part of a post-graduate curriculum in conjunction with health professions or science institutions.

As used in this subsection, the term "health professionals and scientists" is intended to apply broadly to the range of scientific disciplines which are relevant to the regulatory responsibilities of the FDA vis-a-vis food, drugs, medical devices, and cosmetics. Thus the term embraces such disciplines as toxicology, nutrition, food science, and microbiology, as well as the array of other disciplines

which are most relevant to the regulation of pharmaceuticals and medical devices.

Subtitle B "Training Grants for Scientist" provides the authority for the Commissioner to enter into agreements for the repayment of loan obligations on behalf of individuals who have completed a curriculum leading to a speciality in regulatory review medicine and are willing and able to be assigned to a position by the Commissioner of the Food and Drug Administration for a period of time commensurate with the level of loan payment.

The Public Health Service (PHS) Act provides authorities in several different sections which relate to the award of grants and to traineeships provided through grants. Under currently delegated broad authority, the Commissioner can award grants for research, investigation, and testing programs as well as health information and health promotion programs. Although the Commissioner has this broad authority to award grants, he does not currently have the specific authority under those sections of the Act to award grants for training in regulatory review medicine. The sections of the PHS Act perrtaining to grant awards either identify another PHS agency or agencies and their activities without authority currently being delegated to FDA, or the provisions are limiting and preclude FDA's participation.

The Committee believes that in order to continue to protect the public health it is vitually important that the FDA be provided the necessary authority under Title VIII to award multi-purpose training grants to one or more academic institutions to develop a core curriculum program which will be used to train individuals in the field of regulatory review medicine. Many of the areas now regulated by FDA involve products that were unknown when the Food, Drug, and Cosmetic Act was enacted in 1938. The Congress and the American public expert FDA to keep pace with what it regulates.

In recent years FDA has reviewed and approved increasing numbers of products developed through biotechnology—a revolutionary new type of bioscience which was generated revolutionary pharmaceuticals and devices. Similarly, the Agency is currently evaluating new food products such as sweeteners and fats formulated through radically new technological processes.

In the immediate future, FDA will need additional personnel who are trained in the latest technologies in order to respond to the new challenges confronting the Agency. One such challenge is AIDS. The review of all new drug applications continues to be a very high priority for FDA. The Agency has placed special emphasis on producing the most timely, effective, and efficient research and premarketing review possible of products that offer promise for treating, curing, or preventing AIDS or AIDS-related diseases. The Committee believes that it is a critical to assure sufficient drug reviews to process expeditiously all Investigational New Drug Applications, New Drug Applications and applications for licensing of AIDS products and vaccines. The Agency, particularly under the leadership of its present Commissioner, Frank E. Young, has established innotative measures to help expedite the development, testing, review, an dapproval of promising drugs, vaccines, and diagnostics for this disease. Several critically important AIDS-related

products have been developed and approved in record breaking time.

The Agency's success in this instances does not, however, mitigate the problems that it now faces. In order to access a new generation of biotech drugs and computer-driven medical devices, FDA's scientific base must be continually revitalized to keep abreast of the latest technological advances.

TITLE VII—SCIENTIFIC REVIEW GROUPS

This Committee supports allowing the Commissioner of the FDA to be select members of scientific review groups to assist in reviewing FDA activities and in making recommendations on various issues at FDA. Such scientific review groups shall be exempt from the provisions of the Federal Advisory Committee Act. This provision is consistent with other Public Health Service Agencies, including ADAMHA and NIH.

While the Committee has made provisions that the Commissioner may pay for individuals to participate on Scientific Review groups it is the Committee's expectation that such authority will only be used in rare cases for those members who do not have adequate resources to participate as a member of a review group.

TITLE VIII—HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE

The Committee notes that the FDA will play a major, evolving role in the growing area of human food technology. In addition, the FDA needs to be responsive to new approaches in food technology and production, food reseach and development, biotechnology and food products, food safety, health related claims for food for human consumption, and most importantly the relationship between diet, nutrition and health.

In a report by the General Accounting Office received by the Committee on June 13, 1989, it was noted that the FDA is not making use of current automation technology in managing the activities of the FDA. The Committee notes that the FDA does have several demonstration programs underway with the pharmaceutical industry to evaluate the effectiveness of computerization of new drug applications. The Committee encourages the FDA to speed up the process of accepting applications through the use of automation technology.

TITLE XII—PLAN OF MANAGEMENT INITIATIVES

As a follow-up to the GAO Report on FDA Resources issued in September 1989 the Committee has directed that the FDA enter into a contract for a study of the management initiatives needed to assess, prioritize, and improve the efficiency and productivity of the activities of the FDA. The Committee has also directed that the plan shall provide for identifiable and measurable goals and objectives.

The Committee expects that the management activities undertaken by the FDA will at a minimum:

(1) Project performance levels for the Agency based on at least four resource levels, only one of which is below the current level of funding;

(2) Determine which of the agencies responsibilities either can more efficiently be performed by the private sector, other Federal or State agencies, or because of changes in technology or science no longer need to be regulated by the FDA;

(3) Develop and implement a time specific strategy for a management information system for the Agency that includes a plan to fully automate the applications, records, and approval process for products regulated by the Agency. The plan should also include a description of the resources needed by the Agency, the cost impact on the regulated industries, and impact on the Agency's data collection budget;

(4) Develop a dynamic automated internal management system to provide ongoing information on staff, including but not limited to productivity, turnover, training, needs, and the physical, fiscal, and human resource needs; and

(5) Provide a timetable for implementing changes in staffing, data systems, and management and include information on other issues deemed important to the agency.

The Committee urges the FDA to involve those industrial sectors regulated by the Agency in the development of the plan.

IV. Committee Action

S. 845 was considered by the Committee on November 1, 1989, and reported favorably with an amendment in the nature of a substitute, by unanimous vote.

V. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, November 9, 1989.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources, U.S. Senate,
Washington, DC.

Dear Mr. Chairman: The Congressional Budget office has prepared the attached cost estimate for S. 845, the FDA Revitalization Act, as ordered reported by the Senate Committee on Labor and Human Resources on November 1, 1989.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Robert D. Reischauer,
Director.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 845.
2. Bill title: FDA Revitalization Act.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on November 1, 1989.

4. Bill purpose: To amend the Federal Food, Drug, and Cosmetic Act to revitalize the Food and Drug Administration, and for other purposes.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1990	1991	1992	1993	1994
Estimated authorization levels:					
Consolidated administrative and laboratory facility	500.0				
Senior Scientific Health Service	15.3	16.0	16.8	17.6	18.4
Small business assistance	18.0	18.0	18.0		
Biotechnology demonstration	10.0	10.5	10.9		
Training program	4.0	4.2	4.4		
Loan repayment program	2.0	2.0	2.0		
Scientific review groups	1.0	1.1	1.1	1.1	1.2
Advisory committee	.5	.5	.6	.6	.6
Automation of FDA	10.0	10.5	10.9	11.4	12.0
Study	.5	.5			
Total estimated authorization levels	561.3	63.2	64.7	30.7	32.2
Estimated outlay levels:					
Consolidated administrative and laboratory facility	20.0	85.0	165.0	195.0	35.0
Senior Scientific Health Service	7.6	15.6	16.4	17.2	18.0
Small business assistance	7.4	16.7	18.0	10.6	1.3
Biotechnology demonstration	4.1	9.5	10.6	6.4	.8
Training program	1.6	3.8	4.3	2.6	.3
Loan repayment program	.8	1.9	2.0	1.2	.1
Scientific review groups	.4	1.0	1.1	1.1	1.2
Advisory committee	.2	.5	.5	.5	.6
Automation of FDA	4.1	9.5	10.6	11.1	11.6
Study	.2	.5	.3		
Total estimated outlay levels	46.5	143.9	228.7	245.7	68.8

Details in this table may not add to totals because of rounding. The costs of this bill fall within budget function 550.

Basis of estimate: This cost estimate only includes those provisions assumed to have a budgetary impact. In addition, the estimate assumes that the 1990 authorization is fully appropriated by April 1990. The 1991 through 1994 estimated authorization levels are assumed to be fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

S. 845 would authorize the design, construction and operation of a consolidated administrative and laboratory facility for the Food and Drug Administration (FDA). Officials at FDA envision an entire consolidated FDA campus and estimate the cost of the construction would be approximately $500 million dollars.

The bill would authorize the Secretary of Health and Human Services (HHS) to create a Senior Biomedical Health Service program. This program would raise the salary limit for senior scientists involved in biomedical, behavioral or clinical research in the attempt to retain these scientists within the Public Health Service. The Public Health Service estimates that approximately 780 scientists would fall into this category and that the average initial salary increase would be about $19,600 for each scientist. There-

fore, the CBO estimates that this program would cost approximately $15.5 million in 1990, increasing to about $18.5 million in fiscal year 1994 due to projected pay inflation.

S. 845 would authorize appropriations of $18 million in each of the fiscal years 1990 to 1992 for small business training and technical assistance. In addition, the bill specifies an authorization of $10 million in fiscal year 1990 and such sums as nesessary in fiscal years 1991 and 1992 for a biotechnology demonstration project. The 1991 and 1992 amounts were estimated by increasing the 1990 level for projected inflation.

The Secretary of HHS would be authorized to make training grants to academic institutions to establish core curriculum programs in the regulatory review field. The bill specifies an authorization level of $4 million in fiscal year 1990 and such sums as necessary in fiscal years 1991 and 1992 for this activity. The 1991 and 1992 levels were estimated by increasing the 1990 level for projected inflation.

In addition, this bill would authorize the establishment of a loan repayment program. In this program, the Secretary of HHS would pay off a student's loan obligations in return for service at the FDA. The bill authorizes $2 million in fiscal year 1990 and such sums as necessary in fiscal years 1991 and 1992 for this program. The 1991 and 1992 levels were estimated by increasing the 1990 level for projected inflation.

S. 845 would establish technical and scientific review groups to advise and assist in carrying out FDA functions. The members of these groups who are not employees of the fedeal government would be compensated for their services. According to FDA officials, it would cost approximately $1 million each fiscal year to establish these review groups.

S. 845 would also establish a Human Food Safety, Technology, and Nutrition Advisory Committee to advise the Commissioner of Food and Drugs on issues involving food. The fifteen voting members of the committee would be compensated at a daily rate for their services as well as for all travel expenses. In addition, the bill authorizes a permanent staff for the committee. The CBO estimates the costs for the committee would be about $500,000.

The bill would authorize the automation of appropirate activities at the FDA. According to officials at FDA, this activity would cost approximately $10 million in fiscal year 1990, increasing to about $12 million in fiscal year 1994 due to projected inflation.

The bill would authorize the Secetary of HHS to contract for a study of the initiatives undertaken by FDA's management to improve the efficiency and productivity of their agency. FDA officials estimate that the study would cost no more than $500,000 in both fiscal years 1990 and 1991.

6. Estimated cost to State and local government: None.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Karen Graham.

10. Estimate approved by: C.G. Nuckols, for James L. Blum, Assistant Director for Budget Analysis.

VI. Regulatory Impact Statement

The Committee has determined that there will be minimal or no increase in the regulatory burden of paperwork as a direct result of this bill.

VII. Section-by-Section Analysis

S. 845—FDA Revitalization Act As Reported by the Senate Committee on Labor and Human Resources

Section 1. Short title; table of contents

Section 1 subsection (a) (Short Title) cites the bill as the "FDA Revitalization Act."

Subsection (b) provides a table of contents of the bill.

Section 2. References to the Federal Food, Drug, and Cosmetic Act

Section 2 states that the terms "amendment to" or "repeal of" in the bill will be considered to refer to amendment to or repeal of sections of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless otherwise specified.

TITLE I—CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY

Section 101. Consolidated administrative and laboratory facility

Section 101 adds a new "Section 710—Consolidated Administrative and Laboratory Facility" to Chapter VIII of the Federal Food, Drug, and Cosmetic Act (FFDC Act).

New section 710 subsection (a) (Authority) gives the Secretary of Health and Human Services authority, in consultation with the Director of the General Services Administration, to enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

New subsection (b) (Awarding of Contract) directs the Secretary to solicit contract proposals and to give priority to proposals that are the most cost effective for the Federal government and allow for the use of donated land, Federally owned property, or lease-purchase arrangements. A contract must result in a net cost savings to the government over the duration of the contract, as compared to the purchase price for the government, including borrowing by the Secretary of Treasury.

TITLE II—SENIOR SCIENTIFIC HEALTH SERVICE

Section 201. Senior Scientific Health Service

Section 201 amends Part A of Title III of the Public Health Service Act by inserting after section 301 (42 U.S.C. 241) a new "Section 301A. Senior Scientific Health Service."

New section 301A, subsection (a) (Establishment) authorizes the Secretary to establish a Senior Scientific Health Service.

New subsection (b) (Membership) describes the membership of the Service. Members will be appointed by the Secretary without regard to the normal provisions of the competitive civil service and

based solely on distinction and achievement in the field of biomedical research or clinical research evaluation.

New subsection (c) (Duties) provides that members of the Service will be assigned duties that require expertise in biomedical research, behavioral research, or clinical research evaluation. Members may also be assigned to supervise other scientists in such duties.

New subsection (d) (Compensation) provides for members of the Service to receive salaries of up to 110 percent of annual salaries presently in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

New subsection (e) (Retirement) provides for continuity of service for purposes of retirement for individuals who may transfer into the service from the Public Health Service Corps.

Conforming amendments are made to section 5948(g)(1) of title 5, United States Code.

TITLE III—RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS

Section 301. Recovery and retention of fees for FOIA requests

Section 301 amends Chapter VII of the FFDC Act (21 U.S.C. 371 et seq.) (as amended by section 101) by adding a new "Section 711. Recovery and Retention of Fees for Freedom of Information Requests."

New section 711 subsection (a) authorizes the Secretary, acting through the Commissioner of Food and Drugs, to charge fees for requests under the FOIA that are adequate to recover all reasonable costs incurred in processing the requests; to retain these fees; and to establish an accounting system with procedures for handling receipts and expenditures of these fees.

New subsection (b) (Use of Fees) directs the Secretary and the Commissioner of Food and Drugs to use fees collected for FOIA requests only for funding activities related to processing FOIA requests.

New subsection (c) (Waiver of Fees) affirms the right of requesters to obtain waivers of fees as provided for in the FOIA.

TITLE IV—SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE

Section 401. Small business training and technical assistance

Section 401 amends Chapter VII of the FFDC Act (21 U.S.C. 371 et seq.) (as amended by sections 101 and 301) by adding a new "Section 712. Small Business Training and Technical Assistance."

New section 712 subsection (a) directs the Secretary to establish an FDA Office to provide technical and other nonfinancial assistance to small manufacturers of FDA-regulated products to help them to comply with the requirements of the FFDC Act.

New subsection (b) (Authorization Appropriations) authorizes an appropriation of $18 million to FDA for each fiscal year from 1990 through 1992 to provide this assistance.

TITLE V—BIOTECHNOLOGY DEMONSTRATION PROJECT

Section 501. Biotechnology demonstration project

Section 501 amends Chapter VII of the FFDC Act (21 U.S.C. 371 et seq.) (as amended by sections 101, 301, and 401) by adding a new "Section 713. Biotechnology Demonstration Project."

New section 713 subsection (a) authorizes the Secretary to work with and use the facilities of a public or private cooperative to set up a demonstration project for the purpose of promoting the development of biotechnology.

New subsection (b) (Regulations) authorizes the Secretary to issue implementing regulations for section 713.

New subsection (c) (Authorization of Appropriations) authorizes an appropriation of $10 million for fiscal year 1990 to carry out this section and such sums as are necessary for each of the fiscal years 1991 and 1992.

TITLE VI—TRAINING AND LOAN REPAYMENT PROGRAMS

Section 601. Training and loan repayment programs

Section 601 amends the FFDC Act (21 U.S.C. 301 et seq.) by adding a new "Chapter X—Training and Loan Repayment Programs."

New Chapter X, Subchapter A—Training Program provides for grants and contracts related to development of core curriculum programs in the field of regulatory review amd training of individuals in regulatory review.

New Subchapter A section 1001. Authority authorizes the Secretary to make grants to or enter into contracts with public or nonprofit academic institutions, including schools of medicine, dentistry, pharmacy, public health, and food science, for the purpose of designing and developing a core curriculum programs to train individuals in the field of regulatory review.

New section 1002. Requirements subsection (a) provides that grants will be awarded upon submission of an application by an institution and approval by the Secretary, with the institution providing satisfactory formal assurances that individuals receiving funds through the institution under such grants will meet the service requirements set forth in new section 1004.

New subsection (b) (Application) provides that applications for grants must meet requirements for form, content, and submission as set forth in regulations issued by the Secretary.

New section 1013. Use of Grants provides that an institution receiving a grant under this subchapter must use the grant to design and develop a core curriculum program in regulatory review. The institution may, in addition, use the grant to provide stipends, tuition, fees, and allowances to individuals who participate in the regulatory review program.

New section 1004. Requirement of Service sets forth requirements for individuals who receive funds under a regulatory review grant.

New section 1004 subsection (a) requires each individual who receives funds from an institution through a regulatory review grant

to serve for a period of time as an employee of the Food and Drug Administration.

New subsection (b) (Period of Required Service) sets the required period of service with the Food and Drug Administration at two months of service for each month in which funds were received.

New subsection (c) (Compliance) authorizes the Secretary to state in regulations a reasonable period of time in which individuals to whom this section applies must begin their required service with FDA.

New subsection (d) (Failure to Comply) states that the United States will be entitled to recover funds from an individual who fails to comply with the requirement for service with FDA within the specified time period. The Secretary will issue regulations containing a formula for determining the amount to be recovered.

New section 1005. Authorization of Appropriations authorizes an appropriation of $4 million and such sums as are necessary for fiscal years 1991 through 1992 to carry out Subchapter A.

New Subchapter B—Loan Repayment Program contains new sections as follows:

New section 1011. Loan Repayment Program provides for the Secretary to establish a loan repayment program for the purpose of repaying loans incurred by individuals to obtain training in regulatory review in exchange for serving a period of time as FDA employees.

New section 1012. Administration contains the following subsections relating to administation of the loan repayment program provided for in Subchapter B.

New subsection (a) (Regulations) provides for the Secretary to issue within a year regulations that prescribe eligibility for the loan repayment program, dissemination of applications to participate in the program, a contract for participation in the program, costs that may be paid through the contract, and all other information necessary to carry out the repayment program.

New subsection (b) (Relationship to National Health Service Corps Loan Repayment Program) provides that the Secretary will carry out the loan repayment program, to the extent practicable, in a way that is consistent with the National Health Service Corps Loan Repayment Program established under the Public Health Service Act.

New subsection (c) (Employment Ceiling) provides that individuals participating in regulatory review training, under a contract as provided for in this new chapter, will not count against any employment ceiling affecting the Department of Health and Human Services.

New section 1013. Authorization of Appropriations authorizes $2 million for each fiscal year from 1990 through 1992 to carry out the loan repayment program.

TITLE VII—SCIENTIFIC REVIEW GROUPS

Section 701. Scientific review groups

Section 701 of the bill adds a new "section 903. Scientific Review Groups" to Chapter IX of the FFDC Act (21 U.S.C. 391 et seq.). This new section authorizes the Commissioner of Food and Drugs to es-

tablish technical and scientific review groups as needed to carry out the functions of the Food and Drug Administration, to appoint members of these review groups, and to pay all members, except those who are Federal employees.

TITLE VIII—HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE

Section 801. Human Food Safety, Technology, and Nutrition Advisory Committee

Section 801 of the bill adds a new "section 413. Human Food Safety, Technology, and Nutrition Advisory Committee."

New section 413 subsection (a) (Establishment) authorizes the Secretary to establish the Human Food Safety, Technology, and Nutrition Advisory Committee.

New subsection (b) (Composition) provides that the Advisory Committee will consist of 15 members appointed by the Secretary. In making these appointments, the Secretary will consult with the Secretary of Agriculture and will ensure that these 15 members include consumers; food industry representatives; and experts in the fields of food technology and food production, nutrition, food safety, and the application of biotechnology to food products.

New subsection (c) (Duties) states that the Advisory Committee is to advise the secretary and the Commissioner of Food and Drugs on issues relating to food technology and production; food research and development; biotechnology and food products; food safety; the relationship between diet, nutrition, and health; and health related claims made for food for human consumption.

New subsection (d) (Terms) sets the term of an Advisory Committee member at 3 years, except that, of the 15 members first appointed, 5 are to be appointed for a term of 1 year, 5 for a term of 2 years, and 5 for a term of 3 years.

New subsection (d) (Terms) sets the term of an advisory Committee member at 3 years, except that, of the 15 members first appointed, 5 are to be appointed for a term of 1 year, 5 for a term of 2 years, and 5 for a term of 3 years.

New subsection (e) (Support) provides for the Commissioner of Food and Drugs to provide the Advisory Committee with clerical and professional staff support and with information.

New subsection (f) (Travel Expenses) authorizes travel expenses, including per diem in lieu of subsistence, for Advisory Committee members serving away from home, consistent with the authorization of such expenses for intermittent employees (under section 5703 of title V, U.S.C.).

TITLE IX—AUTOMATION OF FDA

Section 901. Automation of FDA

Section 901 of the bill adds to Chapter VII of the FFDC Act (21 U.S.C. 371 et seq.) (as amended by sections 101, 301, 401, and 501 of this Act), a new "Section 714. Automation of Food and Drug Administration."

New section 714 subsection (a) authorizes the Secretary to automate appropriate FDA activites to ensure timely product review.

New section 714 subsection (a) authorizes the Secretary to automate appropriate FDA activities to ensure timely product review.

New section (b) (Authorization of Appropriations) authorizes funds for this automation to be appropriated each fiscal year.

TITLE X—COMPENSATION AND EMPLOYMENT REQUIREMENTS FOR FDA AND EPA SCIENTISTS

Section 1001. Compensation and employment requirements for FDA and EPA scientists

Section 1001 of the bill authorizes the Director of the Office of Personnel Management to take action as necessary to assure that FDA and EPA levels of compensation and employment requirements for scientists are comparable.

TITLE XI—FUNDING FLOOR FOR FDA

Section 1101. Funding floor for FDA

Section 1101 of the bill authorizes an appropriation of no less than $500 million each fiscal year to carry out the activities of FDA, other laws notwithstanding.

TITLE XII—PLAN OF MANAGEMENT INITATIVES

Section 1201. Plan of management initatives

Section 1201 subsection (a) of the bill directs the Secretary, within a year of enactment, to act through the Commissioner of Food and Drugs to contract for a study of management initiatives to improve the efficiency and productivity of the Food and Drug Administration. The study will provide for identifiable goals and measurable objective.

Subsection (b) (Authorization of appropriations) authorizes the appropriation of funds in fiscal years 1990 and 1991 to carry out this study.

VIII. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part of section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Federal Food, Drug, and Cosmetic Act

* * * * * * *

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

Sec. 401–412. * * *

SEC. 413. HUMAN FOOD SAFETY, TECHNOLOGY, AND NUTRITION ADVISORY COMMITTEE.

(a) Establishment.—The Secretary shall establish an advisory committee which shall be known as the "Human Food Safety, Tech-

nology, and Nutrition Advisory Committee" (hereinafter in this section referred to as the "Advisory Committee").

(b) COMPOSITION.—

(1) IN GENERAL.—The Advisory Committee shall consist of 15 members appointed by the Secretary.

(2) MEMBERSHIP.—In making appointments under paragraph (1), the Secretary shall—

(A) consult with the Secretary of Agriculture; and

(B) ensure that the membership of the Advisory Committee includes—

(i) consumers who are not otherwise represented under this subparagraph;

(ii) representatives of the food industry;

(iii) experts in the field of food technology and food production;

(iv) experts in the application of biotechnology to food products;

(v) experts in the field of nutrition; and

(vi) experts in the field of food safety.

(c) DUTIES.—The Advisory Committee shall advise the Secretary and the Commissioner of Food and Drugs on issues involving food for human consumption, including issues relating to—

(1) food technology and production;

(2) food research and development;

(3) biotechnology and food products;

(4) food safety;

(5) the relationship between diet, nutrition, and health; and

(6) health-related claims for food for human consumption.

(d) TERMS.—A member of the Advisory Committee shall be appointed for a term of 3 years, except that of the members first appointed, 5 members shall be appointed for a term of 1 year, 5 members shall be appointed for a term of 2 years, and 5 members shall be appointed for a term of 3 years, as determined by the Secretary.

(e) SUPPORT.—The Commissioner of Food and Drugs shall provide the Advisory Committee with such professional and clerical staff and information as may be necessary for the Advisory Committee to carry out this section.

(f) TRAVEL EXPENSES.—A member of the Advisory Committee, while so serving away from the home or regular place of business of the member, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized under section 5703 of title 5, United States Code, for employees serving intermittently.

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CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701–709. * * *

SEC. 710. CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY.

(a) AUTHORITY.—The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated

Food and Drug Administration administrative and laboratory facility.

(b) AWARDING OF CONTRACT.—The Secretary shall solicit contract proposals under subsection (a) from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal government and that allow for the use of donated land, Federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal government over the duration of the contract, as compared to the government purchase price including borrowing by the Secretary of Treasury.

SEC. 711. RECOVERY AND RETENTION OF FEES FOR FREEDOM OF INFORMATION REQUESTS.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may—

(1) set and charge fees to recovery all reasonable costs incurred in processing requests made under section 552 of title 5, United States Code, for records obtained or created under this Act or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for such requests; and

(3) establish as accounting system and procedures to control receipts and expenditures of fees received under this section.

(b) USE OF FEES.—The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1). Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this Act.

(c) WAIVER OF FEES.—Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5, United States Code.

SEC. 712. SMALL BUSINESS TRAINING AND TECHNICAL ASSISTANCE.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices, drugs, cosmetics, and foods to assist the manufacturers in complying with this Act.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $18,000,000 for each of the fiscal years 1990 through 1992.

SEC. 713. BIOTECHNOLOGY DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall establish and carry out a demonstration project under which the Secretary shall use the facilities of a public or private cooperative, with the permission of any such cooperative and in conjunction with such cooperative, to promote the development of biotechnology.

(b) REGULATIONS.—The Secretary shall issue such regulations as are necessary to carry out this section.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for fiscal year 1990 and such sums as are necessary for each of the fiscal years 1991 and 1992.

SEC. 714. AUTOMATION OF FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this Act.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

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CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

SEC. 901. * * *

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SEC. 903. SCIENTIFIC REVIEW GROUPS.

Without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this Act); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

CHAPTER X—TRAINING AND LOAN REPAYMENT PROGRAMS

Subchapter A—Training Program

SEC. 1001. AUTHORITY.

The Secretary may make grants to, or enter into contracts with, public or nonprofit academic institutions (including schools of medicine, dentistry, pharmacy, public health, and food science) to enable such institutions to design and develop core curriculum programs that will be used to train individuals in the field of regulatory review.

SEC. 1002. REQUIREMENTS.

(a) IN GENERAL.—No grant shall be awarded under this subchapter unless—

(1) the institution has submitted to the Secretary an application for a grant and the Secretary has approved the application; and

(2) the institution provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that individuals receiving funds through the institution under such grants will meet the service requirement of section 1004.

(b) APPLICATION.—An application for a grant submitted under subsection (a) shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

SEC. 1003. USE OF GRANTS.

An institution that receives a grant under this subchapter—

(1) shall use such grant to—

(A) design and develop a core curriculum program that has as its primary emphasis regulatory review; and

(B) train health professionals and scientists in regulatory review; and

(2) may use such grant to provide stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), to individuals who participate in the regulatory review program developed with funds provided under this subchapter.

SEC. 1004. REQUIREMENT OF SERVICE.

(a) IN GENERAL.—Each individual who receives funds from an institution through a grant provided under this subchapter shall, in accordance with subsection (c), serve an obligated period of time as an employee of the Food and Drug Administration.

(b) PERIOD OF REQUIRED SERVICE.—For each month for which an individual receives funds in accordance with subsection (a), such individual shall remain employed for 2 months with the Food and Drug Administration.

(c) COMPLIANCE.—The requirements of this section shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of the training of such individual under the grant received under this subchapter, as the Secretary shall by regulation prescribe.

(d) FAILURE TO COMPLY.—If any individual to whom this section applies fails, within the period prescribed under subsection (c), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with a formula prescribed through regulations issued by the Secretary.

SEC. 1005. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subchapter $4,000,000 for fiscal year 1990 and such sums as may be necessary for each of the fiscal years 1991 through 1992.

Subchapter B—Loan Repayment Program

SEC. 1011. LOAN REPAYMENT PROGRAM.

The Secretary shall establish a loan repayment program under which the Secretary shall repay loans incurred by individuals to obtain training in regulatory review in exchange for the individuals

serving a period of time as employees of the Food and Drug Administration.

SEC. 1012. ADMINISTRATION.

(a) REGULATIONS.—Not later than 1 year after funds are first made available to carry out this subchapter under section 1013, the Secretary shall issue such regulations that are necessary to carry out this subchapter, including regulations prescribing eligibility for the loan repayment program, the method of disseminating applications to participate in the program, the content of a contract entered into to participate in the program, costs that are eligible for payment through the contract, and such other information as is necessary to carry out the program.

(b) RELATIONSHIP TO NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.—The Secretary shall carry out the loan repayment program established under this subchapter, to the extent practicable, in a manner that is consistent with the National Health Service Corps Loan Repayment Program established under section 338B of the Public Health Service Act (42 U.S.C. 254l–1).

(c) EMPLOYMENT CEILING.—Notwithstanding any other provision of law, an individual who has entered into a written contract with the Secretary under this subchapter, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

SEC. 1013. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subchapter $2,000,000 for each of the fiscal years 1990 through 1992.

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PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. * * *

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SEC. 301A. SENIOR SCIENTIFIC HEALTH SERVICE.

(a) ESTABLISHMENT.—The Secretary may establish a Senior Scientific Health Service (hereinafter in this section referred to as the "Service").

(b) MEMBERSHIP.—

(1) CIVIL SERVICE.—An individual chosen to serve in the Service shall not be a part of the competitive service established under chapter 33 of subpart B of part I of title 5, United States Code.

(2) APPOINTMENT.—A person may be appointed to the Service by the Secretary based solely on distinction and achievement of

the person in the field of biomedical research or clinical research evaluation.

(c) DUTIES.—A member of the Service shall be assigned to duties that require expertise in biomedical research, behavioral research, or clinical research evaluation, and may also be assigned to supervise other scientists in carrying out the activities described in this subsection.

(d) COMPENSATION.—An individual selected to serve on the Service by the Secretary under subsection (b) shall be compensated at a rate not in excess of 110 percent of the annual rate of pay in effect for level I of the Executive Salary Schedule established in section 5512 of title 5, United States Code.

(e) RETIREMENT.—For purposes of section 211, the continuous service in the Service of any person who commences such service on termination of service as a commissioned officer in the Public Health Service Corps may be treated as service as a commissioned officer in the Public Health Service Corps and shall not be considered as service that is subject to any other retirement system for officers and employees of the Federal Government.

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TITLE 5, UNITED STATES CODE

TITLE 5—GOVERNMENT ORGANIZATION AND EMPLOYEES

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§ 5948. Physicians comparability allowances

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(H) section 1202 of the Panama Canal Act of 1979, relating to the Panama Canal Commission; **[**or**]**

(I) section 2 of the Act of May 29, 1959 (Public Law 86–36, as amended, 50 U.S.C. 402 note), relating to the National Security Agency; **[**and**]** *or*

(J) section 301A of the Public Health Service Act, relating to the Senior Scientific Health Service.

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